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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/586,665

07/20/2006

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EXAMINER

BRUTUS, JOEL F

ART UNIT

PAPER NUMBER

3768

MAIL DATE

DELIVERY MODE

12/23/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/586,665	Applicant(s) AZUMA ET AL.	
	Examiner JOEL F. BRUTUS	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/20/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramamurthy et al (US Pat: 6,193,659) in view of Hunt et al (US Pat: 6,497,665).

Regarding claims 1-3, Ramamurthy et al teaches an ultrasonic system that transmit signals that sum in the acoustic domain with reduced energy at harmonic imaging frequencies usually at 1st, 2nd, third, fourth and other harmonics of the fundamental [see column 4 lines 45-54] that is pertinent to the claimed invention. Ramamurthy et al further teaches transmit waveforms that are controlled by input information corresponding to time delays, number of cycles, amplitude level and duty cycle. Ramamurthy et al teaches a transmit beam former and a transducer that have broadband response and are capable of transmitting the maximum allowable acoustic power densities [see column 4 lines 57-67]; ultrasonic energy echoed by the subject at the harmonic is received by the transducer [see column 5 lines 8-10]; harmonic image structure within the subject that may be generated by tissue harmonic response or by non-linear contrast agents which may be provided within the subject. Contrast agent

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harmonic imaging is associated with harmonic energy generation through interaction of the fundamental energy with the contrast agent [see column 5 lines 24-32].

Ramamurthy et al further teaches a signal generator that receives apodization word used to scale the waveform amplitude levels [see column 7 lines 20-25]; transmit waveforms that are unipolar or bipolar and includes a plurality of pulses [see figs 3-7]; transmit waveform are set to sum together in the acoustic domain, the summed acoustic waveform is shaped to suppress ultrasonic energy in a wide band centered at the harmonic frequency, the summed waveform has an envelope or amplitude that gradually increases to a maximum value and gradually decreases to zero from the maximum [see column 8 lines 51-59]. Four transmit waveforms having four cycles are transmitted from four elements focused at one point in the subject [see column 9 lines 23-28]; a plurality or more transmit waveforms and delays may be used [see column 9 lines 60-67]; phase difference between waveforms may be used such as transmitting every other waveform with 90 degree phase difference [see column 12 lines 46-49]; DAC (digital analog converter), amplifier [see column 15 lines 16-17]; a sequencer, clocked sequence [see column 7 lines 26-29].

Ramamurthy et al doesn't teach microbubble contrast agent.

However, Hunt et al teaches contrast agent microbubbles resonate and emit harmonics of the transmitted frequency. The magnitude of these microbubbles harmonics depends on the magnitude of the excitation signal pulse [see column 2 lines 20-28]; second harmonic response occurs when contrast agent under ultrasonic [see column 2 lines 3-10]; a first amplifier, a second amplifier, a time gain control amplifier

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[see column 4 lines 1-10]; suppressing tissue signal responses at the fundamental frequency of a significant magnitude so that non-linear responses from a contrast image can be detected [see column 11 lines 7-12]. A display configured to receive a non-linear response creates an image of the insonified contrast agent and surrounding tissue [see abstract].

Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to combine these references; for the purpose of increasing visualization, using contrast agent microbubbles because it can be easily detected by an ultrasound transducer, contrast agents produce non-linear responses of greater magnitude than the surrounding tissue; and using harmonic imaging after introducing contrast agents, medical personnel can enhance capability for diagnosing of blood filled tissues and blood flow dynamics with patient's arterial system.

3. Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramamurthy et al (US Pat: 6,193,659) in view of Hunt et al (US Pat: 6,497,665) as applied to claim 1 above and further in view of Hossack et al (US Pat: 5,944,666).

Regarding claims 4-5, all other limitations are taught as set forth by the above combination.

The above combination doesn't teach maximum value is 0.1 MPa for the first sequence and less than 0.1 MPa for the second.

However, Hossack et al teaches second harmonic contrast agent can be used to enhance ultrasonic imaging of blood flow [see column 1 lines 20-21]; destroying micro

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bubbles with a pressure about 2 MPa and 0.2 MPa is sufficient to produce a second harmonic response from these contrast agents for imaging purposes [see column 1 lines 23-28].

Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to combine these references; for the purpose of preventing destruction of microbubbles; and using maximum value of the transmission amplitude of about 0.1 MPa or lower in order to prevent the destruction of contrast agent; and second harmonic contrast agent to enhance ultrasonic imaging of blood flow.

Conclusion

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL F. BRUTUS whose telephone number is (571)270-3847. The examiner can normally be reached on Mon-Fri 7:30 AM to 5:00 PM (Off alternative Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. F. B./
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768